

## **REMARKS**

Applicants thank the Examiner for the courtesy of a personal interview on September 21, 2005.

The following remarks are fully and completely responsive to the Office Action dated May 12, 2005. Claims 1-53, 80-121 and 137-231 are pending in this application.

In the outstanding Office Action, the priority claim was objected to as the specification failed to contain the relationship of the prior nonprovisional applications in the first sentence of the specification; claims 2-21, 106-114, 184-197 and 199-215 were rejected under 35 U.S.C. § 112, first paragraph; and claims 1-53, 80-121 and 137-231 were rejected under 35 U.S.C. § 103(a). Claims 1-53, 80-86, 88-101, 104-121, 137-147, 149-163, and 165-231 are subject to an obviousness-type double patenting rejection over claims 1-82 of U.S. Patent No. 6,542,858. Claims 1-53, 80-114 and 137-231 were also rejected under 35 U.S.C. § 102(f). No new matter has been added. Claims 1-53, 80-121, and 137-231 are presented for reconsideration.

### **Priority**

The Office Action stated that the applicant has not complied with one or more conditions to receiving the benefit of an earlier filing date under 35 U.S.C. § 119(e). Specifically, the Office Action stated that the application failed to state the relationship to the prior nonprovisional applications in the first sentence of the application. Applicants' amendment to the specification includes this reference. Accordingly, Applicants request confirmation that this application now complies with the conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 120.

### **35 U.S.C. § 112, First Paragraph**

Claims 2-21, 106-114, 184-197 and 199-215 were rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. As discussed and agreed to in the personal interview on September 21, 2005, the disclosure on page 22 beginning at line 11 provides support for these claims.

Accordingly, it was agreed that the rejection of claims 2-21, 106-114, 184-197 and 199-215 under 35 U.S.C. § 112, first paragraph, would be withdrawn.

### **35 U.S.C. § 103(a)**

Claims 1-53, 80-121 and 137-231 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Grass (Ref. BW in the Information Disclosure Statement filed July 17, 2001) in view of Gex-Fabry et al. (Ref. BT in the Information Disclosure Statement filed July 17, 2001, "Gex-Fabry"). In making this rejection the Office Action asserts that it would be obvious that the combination of these two references teach and/or suggest each and every element of the claimed invention. The Office Action also asserts that it would be obvious to combine these two references. Applicants disagree and respectfully request reconsideration of this rejection.

Grass teaches a simulation model that successfully predicted oral drug absorption from *in vitro* data. This model was developed for two compounds: ketorolac and ganciclovir. The model used *in vitro* permeabilities of these compounds in various segments of rabbit intestine and the measured solubilities of these compounds in an aqueous solution at the PH of various intestinal segments. Figs. 19 and 20 of Grass show a comparison of actual plasma data to the output of the simulator. As can be seen in these two figures, the model results accurately tracks with the plasma data.

Since Grass uses actual data taken from various intestine segments, Grass has no need to interpolate data from one intestine segment to another intestine segment. Accordingly, Grass does not and cannot teach the regional correlation coefficient recited in claims 2-21, 106-114, 184-187 and 199-215.

The Office Action admits that Grass fails to teach and/or suggest (iv) selecting a new value for the selected adjusted parameter such that the deviation of the comparison in step (iii) is reduced; and (v) replacing the value of the selected adjustment parameter in the simulation model with the new value selected in step (iv). The Office Action asserts that the error correction approaches taught in Gex-Fabry correct these deficiencies in Grass.

While Gex-Fabry teaches a variety of error correction approaches, a person of ordinary skill in the art would not employ these approaches to the simulation model disclosed in Grass. As shown in Figs. 19 and 20, Grass provides an accurate model of the absorption of ketorolac and ganciclovir. Consequently, the model disclosed in Grass has no need for error correction. Therefore, a person of ordinary skill in the art would not combine Grass with Gex-Fabry. Accordingly, Applicants request reconsideration and withdrawal of the rejection of claims 1-53, 80-121 and 137-231 under 35 U.S.C. § 103(a).

### **Double Patenting**

Claims 1-53, 80-86, 88-101, 104-121, 137-147, 149-163 and 165-231 were rejected under the judicially created doctrine of obviousness-double patenting as being unpatentable over claims 1-82 of U.S. Patent No. 6,542,858. The Terminal Disclaimer

filed and paid for on February 14, 2005 renders this rejection moot. A copy of the Terminal Disclaimer filed on February 14, 2005 and a copy of the PTO postcard receipt are enclosed for the Examiner's convenience.

35 U.S.C. § 102(f)

Claims 1, 22-53, 80-105, 137-183, 198 and 216-231 were rejected under 35 U.S.C. § 102(f). As discussed in detail and agreed to in the interview on September 21, 2005, the present application and U.S. Patent No. 6,647,358 have the same inventive entity. Accordingly, the rejection under 35 U.S.C. § 102(f) was withdrawn.

**Conclusion**

Applicants' amendments and remarks have overcome the objections and rejections set forth in the Office Action dated May 12, 2005. Specifically, the amendment to the specification overcomes the objection to the priority claim as not complying with the conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 120. The rejection of claims 2-21, 106-114, 184-197 and 199-215 under 35 U.S.C. § 112, first paragraph, was withdrawn at the interview on September 21, 2005. Applicants' remarks have distinguished claims 1-53, 80-121 and 137-231 from the combination of Grass and Gex-Fabry and thus overcome the rejection of these claims under 35 U.S.C. § 103(a). The Terminal Disclaimer enclosed overcomes the double patenting rejection. The rejection under 35 U.S.C. § 102(f) was withdrawn at the interview on September 21, 2005. Accordingly, claims 1-53, 80-121, and 137-231 are


in condition for allowance. Therefore, Applicants respectfully request consideration and allowance of claims 1-53, 80-121, and 137-231.

Applicants submit that the application is now in condition for allowance. If the Examiner believes the application is not in condition for allowance, Applicants respectfully request the Examiner contact the undersigned attorney by telephone if it is believed that such contact will expedite the prosecution of the application.

In the event that this paper is not considered to be timely filed, Applicants respectfully petition for an appropriate extension of time.

Please charge any fee deficiency or credit any over-payment to Deposit Account No. 01-2300, referring to client/matter number 109904-00015.

Respectfully submitted

  
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Enclosures: Petition for Extension of Time  
Terminal Disclaimer of U.S. Patent No. 6,542,858  
PTO Postcard Receipt